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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,671	08/27/2001	David W. LaFleur	PZ022P1C2	3552

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,671

Applicant(s)

LAFLEUR ET AL.

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1-10,14 and 21** drawn to a polynucleotide from a human-derived expressed sequence tag library, as well as vectors and cells containing said polynucleotide, classified in at least Class 536, subclass 23.1 and Class 435 subclass 243, 320.1, 325, 455. **If this group is elected an election will also be required for the polynucleotide.**
- II. Claim(s) 11-12 and 16** drawn to a purified polypeptide encoded by a polynucleotide from said human-derived expressed sequence tag library, classified in at least Class 530, subclass 350. **If this group is elected, an election will also be required for the polypeptide**
- III. Claim(s) 13** drawn to an antibody specific for a purified polypeptide encoded by a polynucleotide from said human-derived expressed sequence tag library, classified in at least Class 530, subclass 387.1. **If this group is elected, an election will also be required for the polypeptide used to raise the antibody.**
- IV. Claim(s) 15** drawn to a method of producing a purified polypeptide encoded by a polynucleotide from said human-derived expressed sequence tag library, classified in at least Class 435, subclass 69.1. **If this group is elected, an election will also be required for the polypeptide**
- V. Claim(s) 17** drawn to a method of preventing or treating a medical condition which comprises administering a therapeutically effective amount of a polypeptide to a mammalian subject, classified in at least Class 424, subclass 185.1. **If this group is elected, an election will also be required for the polypeptide used in the method.**
- VI. Claim(s) 18** drawn to a method of diagnosing a pathological conditions which comprises determining the presence or absence of a mutation in a polynucleotide, classified in at least Class 435, subclass 6. **If this group is elected, an election will also be required for the polynucleotide analyzed.**
- VII. Claim(s) 19** drawn to a method of diagnosing a pathological conditions which comprises determining the presence or amount of expression of a polypeptide in a sample, classified in at

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least Class 514, subclass 7.1. **If this group is elected, an election will also be required for the polypeptide analyzed.**

VIII. Claim(s) 20 and 23 drawn to a method of identifying a binding partner of a polypeptide, as well as the binding partner identified thereby, classified in at least Class 435, subclass 7.1. **If this group is elected, an election will also be required for the polypeptide used in the binding assay.**

IX. Claim(s) 22 drawn to a method of identifying a biological activity which comprises expressing one of the polynucleotides isolated from a human-derived expressed sequence tag library, classified in at least Class 435, subclass 4. **If this group is elected, an election will also be required for the polynucleotide used in the method.**

X. Claim(s) 24 drawn to a method of preventing or treating a medical condition which comprises administering a therapeutically effective amount of a polynucleotide to a mammalian subject, classified in at least Class 514, subclass 44. **If this group is elected, an election will also be required for the polynucleotide used in the method.**

2. Also note that applicant is hereby required to elect a single sequence for prosecution on the merits (i.e. a single SEQ ID NO. must be elected) because each sequence is a patentably distinct entity with unique structural characteristics.

While this requirement is made in view of the explosive growth of sequence databases in recent years and in view of the fact that searches for multiple sequences per application are now unduly burdensome on the office and its examiners it is proper in light of statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Absent evidence to the contrary, each nucleotide sequences recited in the claims are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature and sequence searches, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN WHISENANT
PRIMARY EXAMINER**